IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF OHIO WESTERN DIVISION

04 SEP 24 PH 4: 41

LUANN PARKER,

Case No. C-1-00-766

Plaintiff,

Judge Susan J. Dlott

v.

PLAINTIFF'S MEMORANDUM

IN OPPOSITION TO

AVENTIS PASTEUR, INC.,

DEFENDANT'S MOTION

FOR SUMMARY JUDGMENT

Defendant.

I. INTRODUCTION

Luann Parker received a flu shot on October 9, 1998; the vaccination was administered by an L.P.N. in a Thriftway grocery store. Soon she began experiencing severe headaches and numbness. She was taken by ambulance to Bethesda North Hospital. In the following months she was hospitalized several times. Her primary care physician, the neurologists at Bethesda North Hospital, and a neurologist from the Cleveland Clinic, each independently diagnosed Ms. Parker with Acute Disseminated Encephalomyelitis (ADEM) caused by the influenza vaccine. One of the neurologists contacted Dr. Carolyn Bridges, a developer of the influenza vaccine at the CDC. She confirmed the diagnosis that Ms. Parker had suffered from ADEM caused by the vaccination. In arriving at their conclusions, each neurologist first ruled out any other plausible diagnoses before concluding that Ms. Parker suffered from ADEM caused by the flu vaccination. These physicians had no interests to promote other than the wellbeing of Ms. Parker; they had not been hired for litigation purposes. Their only goal was to treat a very sick patient.

Defendant's Motion for Summary Judgment asks the Court to ignore all the medical literature on ADEM, the diagnosis of a several Board Certified neurologists, a contemporaneous diagnosis by the CDC, and the temporal relationship between the administration of Defendant's flu vaccine and the onset of symptoms, and substitute its

own opinion that Ms. Parker did not suffer from ADEM.

To demonstrate causation at trial, Ms. Parker must demonstrate by a preponderance of the evidence that the influenza vaccine is capable of causing ADEM and that flu vaccine caused her ADEM in this particular instance. She has done both. Dr. Giesemer's affidavit leaves no doubt that the flu vaccine in question does cause ADEM. This fact is so well established that it is listed as a cause of ADEM in every neurology textbook. David A. Griesemer, M.D., the Director of the Neuroscience Institute at the Medical University of South Carolina, after a careful review of all of Ms. Parker's medical records, concurs with the diagnosis of her treating neurologists. Given the temporal relationship between the administration of the vaccine and the onset of symptoms and the fact supported by the medical record that every other cause was ruled out, it is clear beyond doubt her ADEM was caused by the influenza vaccine. Dr. Griesemer's testimony will assist the jury.

In support of its Motion, Defendant has submitted the affidavit of Dr. Glezen, a physician who states that there are no epidemiological studies that supports the fact that

Despite Defendant's argument to the contrary, there are certain facts in medicine that are true, but are not supported by epidemiological studies.

As Shylock says in his unforgettable response to Salarino:

[&]quot;If you prick us, do we not bleed?

If you tickle us, do we not laugh?

If you poison us, do we not die?"

Act III, Scene 1.

Defendant would require epidemiological studies before it would agree with Shylock.

the influenza vaccine causes ADEM. With all due respect, Dr. Glezen's affidavit is nothing if not disingenuous. What he does not say is that prospective epidemiological studies to establish a causal relationship between for any given year's influenza vaccine and ADEM are impossible. (Affidavit of Dr. Woods)(Exhibit 1)

II. STATEMENT OF RELEVANT FACTS

A. Ms. Parker's Condition

Ms. Parker was a healthy teacher with no neurological problems before October 9, 1998, when she received a Fluzone®² vaccination. Two days later she developed a severe headache, ataxia, vertigo, and tingling in her hands. She also experienced pain in her neck and the back of her head. On October 13, just one day after experiencing the first symptoms, Ms. Parker was taken by ambulance to the emergency room of Bethesda North Hospital with complaints of numbness in her hands, some difficulty thinking and a severe headache. She was discharged from the emergency room that same day. (Exhibit 2)

On October 14, 1998, Dr. Stephen Brewer, Ms. Parker's primary care physician, referred her to Marvin Rorick, M.D., a neurologist. On October 15, 1998, she underwent an MRI examination; the finding of the MRI showed a bilateral posterior parietal enhancement, primarily meningeal in location, with additional, multiple small nodular areas in the deep white matter, which were not enhancing. Dr. Rorick noted in a letter to Dr. Brewer, "This appears to be a mild disequilibrium syndrome which may represent a postvaccination effect." (Exihibit 3) Dr. Rorick was not, and is not, retained for litigation purposes.

3

² This is a split virus (subviron)vaccine manufactured by the Defendant.

Filed 09/2<u>4/2</u>004

Ms. Parker was re-admitted to Bethesda North Hospital on October 21, 1998, with a diagnosis of "acute cerebritis," and a secondary diagnosis of "post influenza vaccine reaction." On October 21, 1998, Dr. Rorick wrote a neurology note that states in part: "Patient is 52 Year old lady in good health until the week of 10/12/1998, within 48 hours of receiving a flu shot at Thriftway in Blue Ash on 10/10. Initial symptoms unsteady gait, numbness in both hands, headache mainly [r] side." On October 25, 1998, Ms. Parker was discharged from Bethesda North Hospital to home, with a principle diagnosis of "encephalitis following immunization procedures." (Exhibit 4)

Ms. Parker was again admitted to Bethesda North Hospital on October 27,1998 for increasing ataxia with titubation and an uninhibited voiding problem; the meningeal enhancement on the MRI during this admission was decreasing. The principle diagnosis explaining her admission was "Post Flu shot Cerebritis." (Exihibit 5)

Dr. Silvania Ng. a neurologist who saw Ms. Parker as a consultant on October 29, 1998, contacted the CDC. Dr. Bridges at the CDC, who was responsible for developing the influenza vaccine, advised that Ms. Parker's condition was attributable to the influenza vaccine. Dr. Bridges was not, and is not, retained for litigation purposes.

Dr. Ng reported in her assessment: "Plan: severe ataxia, Status post flu shot. I did contact the CDC and have talked to Dr. Carolyn Bridges, one of the doctors responsible for the bunch of flu vaccine, and she states that this whole picture could be secondary to the flu shot although is very rare such report . . . " Ms. Parker was discharged from the hospital on November 9, 1998, two weeks later. (Exihibit 6) Dr. Ng was not, and is not, retained for litigation purposes.

Ms. Parker was again admitted on November 14, 1998 as an inpatient to Bethesda North Hospital with a primary admitting diagnosis of "probable deep vein thrombosis of LT (sic) leg." She was given steroids to treat her leg. Ms. Parker was discharged from the hospital on November 17, 1998. (Exihibit 7)

On December 25, 1998, Ms. Parker was taken to the Emergency Room of Bethesda North Hospital with a chief complaint of hearing voices. The psychotic behavior continued, and on December 26, 1998 Ms. Parker was admitted to Bethesda North Hospital with an admitting diagnosis of acute confusional state. (Exhibit 8) During the hospitalization on December 28, 1998, Ms. Parker underwent another MRI; there was a finding of a new small focus of high signal on this MRI, with irregular enhancement in the right frontal-parietal region, with progressive white matter disease in the corona radiata bilaterally when compared to the October 28, 2004 study.

On December 29, 1998 Ms. Parker was transferred to the Cleveland Clinic Foundation Hospital, under Dr. M. Mays' care; during this hospitalization there was a thorough attempt to rule out other problems causing her neurological symptoms. Ms. Parker was discharged to her home from the Cleveland Clinic on January 5, 1999 with the principle diagnosis of ADEM caused by the influenza vaccine. (Exhibit 9) Dr. Mays of the Cleveland Clinic was not, and is not, retained for litigation purposes.

B. Ms. Parker's Expert Witnesses, David A. Greisemer, M.D. and Scott E. Woods, M.D.

David A. Greisemer, a neurologist and a professor of Neurology, has meticulously reviewed Ms. Parker's medical records and MRIs and found that to a reasonable degree

Filed 09/2<u>4/</u>2004

of medical and scientific certainty that her ADEM is the result of the influenza vaccine that she received on October 9, 1998. (Exhibit 10)In addition, Dr. Greisemer has concluded that the thrombosis in her leg was a secondary effect of the vaccination. He based this diagnosis not only on decades of clinical experience diagnosing neurological disorders, but also on the relevant literature in the field with which he is familiar. These include peer-reviewed case studies such as the following:

> Yahr MD and Lobo-Atunes J. Relapsing encephalomyelitis following the use of influenza vaccine. Arch Neurol 1972; 27:182-183;

Ehrengut W and Allerdist H. Über neurologische Komplikationen nach der Influenzaschutz-impfung. Münch med Wschr 1977; 119:705;

Gross WL, Ravens KG, Hansen HW. Meningoencephalitic syndrome following influenza vaccination. J Neurol 1978; 217:219-222; and

Saito H, Endo M, Takase S, Itahara K. Acute disseminated encephalomyelitis after influenza vaccination. Arch Neurol 1980; 37:564-566. (Griesemer Affidavit at Paragraph 15)

Dr. Griesemer has also reviewed several standard neurology textbooks; they all state without reservation that the flu vaccine causes ADEM.

- a. Rowland LP, Merritt's Neurology, 10th edition. Philadelphia: Lippincott Williams & Wilkins, 2000, pp. 151-153, which states, "Acute disseminated encephalomyelitis (ADE) may occur in the course of various infections, particularly the acute exanthematous diseases of childhood, and following vaccinations." It is associated with "vaccination against measles, mumps, rubella, influenza, and rabies." (emphasis added)
- b. Rust R. and Menkes JH. "Autoimmune and postinfectious diseases." In Menkes, JH, Sarnat HB, eds. Child Neurology, 6th edition. Philadelphia: Lippincott Williams & Wilkins, 2000, pp. 641-645, which states, "ADEM can develop after vaccination with a wide variety of killed or attenuated organisms. These include rabies vaccine, Japanese encephalitis, and influenza vaccines." (emphasis added)

- c. Osborne AG. Diagnostic Neuroradiology. St. Louis: Mosby Year Book, 1994, p.704, which says, "Acute disseminated encephalomyelitis (ADEM) is an immune-mediated response to a preceding viral infection or vaccination. ADEM occurs in several settings as follows:
 - 1. Shortly after a specific viral illness, particularly exanthematous childhood diseases such as measles or chicken pox
 - 2. Following a non-specific, presumably viral, upper respiratory infection
 - 3. Following vaccination against rabies, diptheria, smallpox, tetanus, typhoid, or influenza... (emphasis added)

(Griesemer Affidavit at paragraph 10)

According to Dr. Griesemer, the infrequency of ADEM occurrences and the fact that the influenza vaccine changes every year make it very difficult to conduct epidemiological studies.³ Consequently, no epidemiological studies concerning the relationship between ADEM and influenza vaccines exist. (See also the Affidavit of Dr. Woods) (Exhibit 1)

Based on his extensive research of the medical literature, as well decades of experience, and his review of the records of Ms. Parker's treating physicians, Dr. Griesemer concluded to a reasonable medical and scientific certainty that Ms. Parker's ADEM was caused by the influenza vaccine. (Exhibit 10)

Defendant had Mrs. Parker examined by a neurologist it hired for the purpose of litigation. He contends that she suffered some neurological symptoms but he says it is not a classic ADEM. Defendant's expert, however, fails to provide any explanation at all for Ms. Parker's condition. He does admit, however, that Ms. Parker had neurological problems. He denies it was caused by influenza vaccine but is unable to demonstrate or

³ In contrast, the vaccine for MMR and DPT are the same every year and more people have received the vaccine. This allows epidemiologists ample data for studies.

2004

even suggest any alternative explanation for the condition. (Exhibit 11). Even if the court were to ignore every other fact and consider only the affidavits of Dr. Griesemer and Dr. Glezen, it is clear that there in fact exists is a genuine issue of material fact.

III. LEGAL ANALYSIS

A. Summary Judgment Standard

The appositeness of rendering a Summary Judgment rests upon a tri-partite demonstration (1) that there is no genuine issue of material fact; (2) that the moving party is entitled to judgment as a matter of law; and (3) that reasonable minds can come to but one conclusion, and that conclusion is adverse to the party against whom a Motion for Summary Judgment is asserted, who is entitled to have evidence construed most strongly in her favor. F.R. Civ. P. 56(c). Anderson v. Liberty Lobby, Inc., 477 U.S. 242 (1986).

It is beyond dispute that the record in this case proves a causal relationship between Plaintiff's vaccination and her illness. For the purpose of Defendant's Motion, however, Plaintiff only needs to establish that when the evidence is construed strongly in her favor, a reasonable mind could find that Ms. Parker suffered some neurological injury after her vaccination. Celotex Corp v. Catrett, 477 U.S. 317 (1986). Dr. Griesemer and all the other neurologists who treated Ms. Parker state that her neurological injury was ADEM. Defendant's expert concedes that she suffered a neurological injury but argues that it was not a classic ADEM.

Dr. Stephen Brewer, Ms. Parker's primary care physician, Dr. Marvin Rorick, her treating neurologist in Cincinnati, Silvania Ng, M.D., a neurologist consultant who

8

⁴ Defendant's expert's position that Ms. Parker's injury is not a classical ADEM is based in part on the severity of her case. Dr. Griesemer will testify, as will her treating physicians, that it was a severe case of ADEM because of the hemorrhaging that occurred.

examined her, Carolyn Bridges, M.D., one of the doctors at the CDC who was responsible for the development of influenza vaccine, Dr. MaryAnn Mays, Ms. Parker's treating neurologist at the Cleveland Clinic, and Dr. William I. Levin, her current primary care physician, all agreethat the influenza vaccine caused Ms. Parker's ADEM. Defendant's expert neurologist concedes a neurological injury, but says it is not a classic ADEM. The existence of a genuine issue of material fact could not be more profound.

Cognizant of the record's overwhelming evidence, Defendant has raised a novel claim: no one can get sick, her illness diagnosed, and obtain treatment unless there is a epidemiological study of that illness. That is patently absurd. For example, no one doubts that the small pox virus causes small pox, but there are no epidemiological studies to prove it.

Defendant's position that there is no issue of material fact is quite astonishing, given the medical record in this case. Every treating physician came up with the same diagnosis, and none was retained for litigation purposes. When one looks at the treating physicians' diagnosis, none of them were retained for litigation purposes. They were trying to treat a very sick patient. They ran batteries of tests and looked at those tests. Independently of one another they reached the conclusion that Ms. Parker suffered ADEM caused by her vaccination. So much for the issue of acceptability among practitioners. The treating physicians, of course, did more than that; one of them called the CDC and talked to Dr. Bridges, a developer of the vaccine. She confirmed the diagnosis. Defendant, to its credit, has not questioned the diagnosis of these physicians. Their statements are part of the record of this case and their conclusion is unrefuted: Ms.

Parker suffered from ADEM after her vaccination on October 9, 1998. There is a genuine issue of material fact.

When physicians at Bethesda North thought that it was in Ms. Parker's best interest to go to a teaching institution to treat her severe case of ADEM, they sent her to Cleveland Clinic, one of the most respected centers of medical care in the world. What was her diagnosis at the Cleveland Clinic? ADEM caused by the flu vaccine.

B. The Daubert Standard

It is instructive to note that Defendant completely ignores the treating physicians and relies, albeit erroneously, on Daubert v. Merrell Dow, 509 U.S. 579 (1995) to undermine Ms. Parker's diagnosis and the testimony of Dr. Griesemer. Daubert and its progeny do not stand for the proposition that the Defendant claims.⁵ Daubert established the standard that governs the admissibility of expert testimony. In <u>Daubert</u>, plaintiffs brought suit claiming that the use of Bendectine by pregnant mothers caused serious birth defects. Thirty published studies involving over 130,000 patients refuted the plaintiffs' position. Id. at 582. None of these studies had found Bendectin to cause birth defects in human fetuses. Plaintiffs' experts attempted to establish causation through animal studies and reanalysis of the studies that were done on humans. Id. at 583.

Daubert concluded that the judge in a case acts as a gatekeeper, determining whether a purported expert and his or her testimony are reliable enough to be presented to a jury. To fulfill its gatekeeper function, the court makes a preliminary assessment to determine whether the expert testimony falls within the bounds of accepted science.

⁵ The Court is well aware that the name <u>Daubert</u> is being so misused that it has almost lost its significance.

Filed 09/24

The trial judge must determine whether the expert testimony is (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue. In determining whether the proffered expert testimony should be admitted, the Supreme Court in Daubert provided the trial court a non-exclusive list of factors to consider when determining whether expert testimony is reliable enough to be presented to a jury. These factors are: whether the theory can be and has been tested, whether the theory has been subjected to peer review, the known or potential rate of error, and whether the theory or methodology employed is generally accepted in the relevant scientific community. The Supreme Court then stressed the flexibility of these requirements, noting the underlying principles of reliability and relevance. Id at 594-595. The Supreme Court reiterated the flexibility of the Daubert factors in Kuhmo Tire Company, LTD., v. Carmichael 526 U.S. 137 (1999). The ultimate issue remains whether or not the proffered expert testimony will provide assistance to the jury.

C. Ms. Parker's expert will assist the jury to decide whether or not Ms. Parker suffered from ADEM after receiving a flu vaccination; his testimony is reliable under Daubert and its progeny to conclude that Defendant's influenza vaccine caused her ADEM.

The first reliability factor under Daubert asks whether the expert's theory can or has been tested. Here, the answer is a definitive yes! Look at the textbooks. Look at the reports. Defendant ignores all that and only relies on the absence of epidemiological studies, which is quite disingenuous. The flu virus changes every year, as does the flu vaccine. A prospective epidemiological study is impossible because before the epidemiological test is completed the season is over, and the next year there is a new virus and a new vaccine.

Filed 09/24<u>/2</u>004

The rarity of ADEM also contributes to the futility and the cost effectiveness of an epidemiological study. The more rare a phenomenon, the larger the sample sizes need to be for an epidemiological study. ADEM, as a result of a vaccine, occurs so infrequently that the number of individuals needed for this study would be much too large. In this case, therefore, an epidemiological study is virtually impossible. (Exhibit 10) The absence of epidemiological studies, however, does not mean that there is no cause and effect relationship between the flu vaccine and ADEM. In fact, Defendant's expert is careful. He does not and he can not say that there is an epidemiological study that says Fluzone® does not cause ADEM. All he says is that to his best knowledge he does not know of an epidemiological study that says there is a cause and effect relationship. In the absence of an epidemiological study one has to look at other sources, and what better source is there than a textbook of neurology. Every textbook states that

In Rider v. Sandoz Pharms. Corp., 295 F.3d 1194 (11th Cir., 2002) the court concluded that the lack of epidemiological studies were not necessarily fatal to a plaintiff's case. Courts should also look to case studies and learned treatises to establish the reliability of proffered expert testimony. Id. at 1202. This case exhibits both. Dr. Griesemer has rested his opinion on several neurology textbooks as well as several case studies. All of the literature in the medical field indicates that the influenza vaccine causes ADEM. There is not a single textbook that says the opposite. None.

the flu vaccine causes ADEM. Defendant has the burden to establish that every textbook

in neurology is wrong. It has not, and cannot, carry this burden.

In this case, at least four board certified neurologists found a cause and effect relationship when they were trying to treat Ms. Parker. They were not hired guns who

were retained specifically for litigation; they were practitioners who had only one goal: the best interest of their patient. They each concluded that Ms. Parker's illness (ADEM) was caused by her flu shot. If this were not enough, which it clearly should be, Plaintiff retained an expert neurologist who reviewed her medical records as well as the relevant literature. Dr. Griesemer is a board certified neurologist, a clinician, and an academic. He is familiar with the relevant studies and textbooks. His conclusion: the flu vaccine causes ADEM and it caused Ms. Parker's bleeding ADEM.

The second reliability factor under <u>Daubert</u> is whether the theory has been subjected to peer review. The studies documenting the association of influenza vaccines and neurological dysfunction span decades in the peer-reviewed literature. It is now an article of faith in every neurology text. They include the studies listed in Dr. Griesemer's affidavit. Again, the causal relationship is so well accepted that it is in medical textbooks. This fulfills the second reliability factor in <u>Daubert</u>.

The third reliability factor in this case must be viewed from the point of view of all the neurologists who examined Ms. Parker. Dr. Stephen Brewer, Ms. Parker's primary care physician, Dr. Marvin Rorick, her treating neurologist in Cincinnati, Silvania Ng, M.D., a neurologist consult who examined her, Carolyn Bridges, one of the doctors at the CDC who was responsible for development of the influenza vaccine, Dr. M. Mays, Ms. Parker's treating neurologist at the Cleveland Clinic, and Dr. William I. Levin, her current primary care physician, all agree: the influenza vaccine caused Ms. Parker's ADEM. They made their diagnosis only after conducting batteries of tests to eliminate every other possibility. They were so diligent that they even called the CDC to

Filed 09/24<u>/2</u>004

talk to the developer of the vaccine. The possibility that all these highly educated medical minds could be mistaken is nothing less than perposterous.

Defendant's position is made even less tenable when one compares Plaintiff's neurologist with Defendant's neurologist. Defendant's neurologist offered no diagnosis. He simply limited his description to a neurological injury, and did not justify why he though it could not be ADEM. He merely says that it is not classical. Here again, there is a genuine issue of material fact.

Daubert's final reliability factor asks if the theory is widely accepted in the medical community. It is in this case. The association between influenza vaccines and ADEM has been enshrined in Neurology textbooks used in medical schools as well as in Bale JF. "Neurologic complications of immunization." J Child Neurol 2004; 19:405-412, a current review of vaccination effects that states that ADEM is a possible effect of the influenza vaccine. Consequently, this phenomenon has been widely accepted in the medical community.

None of the cases relied upon by the Defendant is relevant to this case. In every case that Defendant cites, the injured party's case was dubious at best!

In Lopez v. Wyeth-Averst Laboratories, 1996 U.S. Dist. LEXIS 22739 (N.D. Ca. 1996), affirmed, 139 F.3d 905 (1998), the court excluded the expert testimony proffered by the plaintiff. That case is radically different than this one because there was epidemiological evidence available that did not support the plaintiff's experts. Here there is no epidemiological evidence one way or the other. Instead there is a wealth of irrefuted proof that supports Ms. Parker's position. When the available epidemiological evidence refutes the testimony of proffered expert witnesses, the court may exclude it. In

Ms. Parker's case, however, this is not the issue; there is no epidemiological evidence refuting her experts. Because the influenza vaccine changes every year, no epidemiological studies have been conducted concerning the relationship between the influenza vaccine that was given in the fall of 1998 and ADEM.

Defendant also points to Novak v. United States, 865 F.2d 718 (6th Cir. 1989) and Conde v. Velsicol Chem. Corp., 24 F.3d 809 (6th Cir. 1994), both pre-Daubert decisions, to argue that Plaintiff lacks causation. In Novak, the plaintiff claimed that the swine flu vaccination administered to her husband caused a condition known as dermatomyositis, which led to his death a few months later. At the time, medical literature stated that the origin of the disease was unknown. The plaintiffs offered no case studies or reports to establish a causal link between the swine flu vaccine and her husband's condition, and none of his treating physicians concluded that the swine flu vaccination had caused his condition. Instead, the plaintiff attempted to analogize her husband's condition to Guillain-Barre Syndrome, a condition thought to be a possible effect of the swine flu vaccination. The Court concluded that this analogy could not adequately support a theory of causation. In addition, the Court found that Mr. Novak's symptoms did not appear until seven or eight weeks after he received the vaccination, creating a weak temporal relationship.

Novak's reasoning mandates the opposite conclusion in this case.. All of her treating physicians, both at Bethesda North Hospital and the Cleveland Clinic Foundation, identified the flu vaccine as the cause of her ADEM. Why? The cause and effect relationship of the flu vaccine to ADEM is so well documented in medical literature that no competent physician could overlook it. The relationship has been

documented in peer-reviewed journals, and is such a well-settled issue that it has been enshrined in standard neurology textbooks.

In Conde, plaintiff sued a chemical company after a third party grossly misapplied termiticide to his home, alleging that the company compromised the health of his family. Not only was the misapplication an intervening and superceding event limiting the liability of the chemical company, but, more importantly, nineteen epidemiological studies refuted the plaintiff's experts. The studies demonstrated that the termiticide posed no health threat at the levels to which the Condes were exposed. Again, Conde mandates an opposite conclusion in this case.

Brock v. Merrell Dow Pharmaceuticals, Inc., 874 F.2d 307, 313 (5th Cir. 1989) is another case that Defendant relies on. Brock, like Daubert, involved the use of Bendectin. Again, there was ample epidemiological evidence to refute the plaintiff's experts. In re Phenylpropanolamine Prods. Liab. Litig., 289 F. Supp. 2d 1230 (D. Wash. 2003) and In re Breast Implant Litigation, 11 F. Supp. 2d 1217 (D. Col. 1998) Allen v. Pennsylvania Eng'g Corp., 102 F.3d 194 (5th Cir. 1996), all featured epidemiological evidence that refuted the testimony of the plaintiff's experts. No such epidemiological studies exist in this case. The medical literature that does exist demonstrates a cause and effect relationship of the flu vaccine to ADEM.

In Hasler v. United States, 718 F.2d 202 (6th Cir. 1983), the plaintiff displayed symptoms like rheumatoid arthritis beginning about ten days after receiving a vaccination for swine flu. The plaintiff's condition displayed many more symptoms that were not associated with rheumatoid arthritis, such as rash, anemia, a heart murmur, and protein

and blood in her urine. Rheumatoid arthritis, moreover, had never been linked to an influenza vaccination. As a result, the court denied plaintiff's appeal.

Unlike in <u>Hasler</u>, in this case all of the medical literature links ADEM to influenza vaccinations. The case studies reviewed by Dr. Griesemer as well as neurology textbooks all give credence to Ms. Parker's claim.

In re Swine Flu Immunization Products Liability Litigation, 533 F. Supp. 567 (D. Colo. 1980) also has very different facts than those of Ms. Parker's case. In that case, the plaintiff developed drop foot after a flu vaccination. The plaintiff in that case suffered from chronic back pain and arthritis, which could also cause left foot drop. In Ms. Parker's case the only explanation for her ADEM is the flu vaccine.

IV. CONCLUSION

According to every treating physician, every peer-reviewed article, and every neurology textbook the flu vaccination causes ADEM. Plaintiff has clearly shown a genuine issue of material fact. Plaintiff respectfully requests that this honorable Court dismiss Defendant's motion for summary judgment and set this matter for trial.

Respectfully submitted,

Firooz T. Namei (0018615) Attorney for Ms. Parker McKinney & Namei Co., LPA *Ratio et Fides* 15 E Eighth St.

Cincinnati, Ohio 45202 Phone: (513) 721-0200

Fax: (513) 632-5898

CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing with Exhibits was served upon John J. Siciliano, Shumaker, Loop, & Kendrick. LLP, 1000 Jackson, Toledo, Ohio 43624-1537 by ordinary U.S. Mail this 23rd day of September, 2004.

Firooz T. Namei